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Does a combination containing morphine and dexamethasone reduce pain after knee replacement surgery?

Submission date
22/01/2022

Recruitment status
No longer recruiting

Registration date
27/02/2022

Overall study status
Completed

Last Edited
25/02/2022

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Total knee arthroplasty (TKA) is surgery to replace the knee joint with an artificial joint. It is considered one of the most successful surgeries with satisfying outcomes, including restored joint movement and significantly reduced pain over time. Patients undergoing TKA typically experience severe pain after surgery, which slows recovery and increases the hospital stay and cost. Injection of a drug cocktail into the joint is a practical and effective pain management strategy after knee and hip surgery. There is no gold-standard cocktail and the proper dosage and composition of the injection cocktail have not been agreed upon. The aim of this study is to evaluate the pain-reducing effectiveness and safety of a morphine and dexamethasone-containing cocktail treatment in patients undergoing total knee arthroplasty.

Who can participate?
Patients aged 50–70 years scheduled for TKA

What does the study involve?
Participants are asked to join this study during hospitalization. They are randomly allocated to one of three groups. Group I patients are injected with morphine, dexamethasone, bupivacaine, flurbiprofen axetil, and normal saline. Patients in group II are injected with dexamethasone, bupivacaine, flurbiprofen axetil, and normal saline. Patients in group III are administered bupivacaine, flurbiprofen axetil, and normal saline. Pain control and active and passive range of movement are recorded. The following side effects are monitored: headache, dizziness, nausea, vomiting, wound leakage, and wound infection.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part but there should be benefits to future patients undergoing TKA because the results of the study are likely to influence which cocktail treatment the surgeon uses. The main risks are the potential complications associated with using opioids and corticosteroids. Therefore, the researchers will set the dosage and compatibility in strict accordance with the drug instructions.

Where is the study run from?
First Affiliated Hospital of Dalian Medical University (China)

When is the study starting and how long is it expected to run for?
January 2018 to May 2021

Who is funding the study?
First Affiliated Hospital of Dalian Medical University (China)

Who is the main contact?
1. Dr Ying Gong, gying202110@163.com
2. Dr Jian Gong, gongjian911@163.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CTR20181569

Study information

Scientific Title
Morphine and dexamethasone incorporated cocktail regimen efficiently reduced postoperative pain in patients undergoing primary total knee arthroplasty

Study objectives

The present study was conducted to evaluate the pain-reducing efficacy and safety of the morphine and dexamethasone incorporated cocktail regimen in patients undergoing total knee arthroplasty (TKA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/06/2018, the research ethics committee of the First Affiliated Hospital of Dalian Medical University (222 Zhongshan Rd, Xigang District, Dalian, Dalian, Liaoning, 116000, China; +86 (0)411 8301 0706; dyyyethics@163.com), ref: YJ-JG-2018

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Postoperative pain in patients undergoing primary total knee arthroplasty

Interventions
This study enrolled 213 patients and randomly assigned them to one of three groups. The randomisation process was simple randomization.

Group I: morphine (5 mg), dexamethasone (5 mg), bupivacaine (10 mg), flurbiprofen axetil (10 mg), and normal saline (20 ml)
Group II: dexamethasone (5 mg), bupivacaine (10 mg), flurbiprofen axetil (10 mg), and normal saline (20 ml)
Group III: bupivacaine (10 mg), flurbiprofen axetil (10 mg), and normal saline (20 ml)

After total knee arthroplasty, the cocktails were injected into the knee cavity once. The total duration of follow-up for all treatment arms was the first 4 days after surgery. To compare the pain-controlling efficiency, the visual analog scale (VAS) score and active and passive range of movement (ROM) were recorded and evaluated. The following side effects were monitored: headache, dizziness, nausea, vomiting, wound leakage, and wound infection.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Morphine, dexamethasone, bupivacaine, flurbiprofen axetil

Primary outcome measure
1. Pain-reducing efficacy measured using the visual analog scale (VAS) score in the first 4 days after TKA surgery
2. Active and passive range of movement (ROM) measured using a physical examination of the knee joint in the first 4 days after TKA surgery

Secondary outcome measures
1. Complications (wound leakage and superficial infection) and other adverse events (cardiac infarction, stroke, and acute renal failure) monitored using renal function tests including serum creatinine (Cr) and blood urea nitrogen (BUN), physical examination, and questioning the patients during hospitalization
2. Potential side effects, including headache, dizziness, nausea, and vomiting, monitored by questioning the patients during hospitalization

Overall study start date
01/01/2018

Completion date
01/05/2021

Eligibility

Key inclusion criteria
Patients aged 50–70 years who were scheduled for elective primary total knee arthroplasty (TKA) were assessed for eligibility. This study included all patients who had been diagnosed with knee osteoarthritis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
250

Total final enrolment
213

Key exclusion criteria
History of knee replacement surgery, hepatic or renal dysfunction, or ischemic heart diseases

Date of first enrolment
04/09/2018

Date of final enrolment
25/10/2020

Locations

Countries of recruitment
China

Study participating centre
First Affiliated Hospital of Dalian Medical University
China
116000

Sponsor information

Organisation
First Affiliated Hospital of Dalian Medical University

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Sponsor type
Hospital/treatment centre

Website
http://www.dmu-1.com/

ROR
https://ror.org/055w74b96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
First Affiliated Hospital of Dalian Medical University

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ying Gong (gying202110@163.com). The type of data: patient general information, VAS score, active ROM, passive ROM, potential side effects, complications, and other adverse events information. The data provided must be anonymised.

IPD sharing plan summary
Available on request